

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DEX-0247 #8
Inventors: Sun et al.
Serial No.: 10/082,828
Filing Date: October 29, 2001
Examiner: Ly, Cheyne D.
Group Art Unit: 1631
Title: Compositions and Methods Relating to
Breast Specific Genes and Proteins

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On June 2, 2003


Kathleen A. Tyrrell, Registration No. 38,350

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Reply to Restriction Requirement

This is a reply to the Restriction Requirement mailed May 1,
2003 setting a one (1) month statutory period for response.
Please enter the following remarks into the record.

REMARKS

Claims 1-17 are pending in the instant application. Claims
1-17 have been subjected to a Restriction Requirement as follows:
Group I, claims 1-5, 7 and 8, drawn to a nucleic acid,

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vector and host cells, classified in classes 435 and 536, subclasses 320.1, 325, 252.3; and 23.1, respectively;

Group II, claim 6, drawn to a method for determining the presence of a breast specific nucleic acid (BSNA) in a sample, classified in class 435, subclass 6;

Group III, claim 9, drawn to a method for producing a polypeptide, classified in class 435, subclass 70.1.

Group IV, claims 10 and 11, drawn to a polypeptide, classified in class 530, subclass 350;

Group V, claim 12, drawn to an antibody, classified in class 530, subclass 387.1;

Group VI, claim 13, drawn to a method for determining the presence of a breast specific protein in a sample using an antibody, classified in class 435, subclass 7.1;

Group VII, claims 14 and 15, drawn to a method and kit for diagnosing and monitoring the presence and metastases of breast cancer in a patient, classified in class 436, subclass 64;

Group VIII, claim 16, drawn to a method for treating a patient with breast cancer, classified in class 514, subclasses 2 and 44; and

Group IX, claim 17, drawn to a vaccine, classified in classes 538 and 530, subclasses 23.1.

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The Examiner suggests that the inventions of Groups I-IX are distinct because they are directed to different chemical types or methods regarding the critical limitations therein.

Further, the Examiner suggests that each of Groups I-IX reads on patentably distinct sequences and further election to a single amino acid/polypeptide sequence or a single nucleotide sequence is required. Specifically, the Examiner suggests that the sequences are unrelated.

Applicants respectfully traverse this Restriction Requirement and sequence election requirement.

With respect to the restriction to Groups I-IX, it is respectfully pointed out that there are two criteria which must be met for a restriction requirement to be proper. See MPEP § 803. The first is that the inventions be independent or distinct. The second is that there would be a serious burden on the Examiner if the restriction is not required. A search of prior art relating to an elected sequence would also reveal any references teaching uses for this sequence. Accordingly, Applicants respectfully disagree with the Examiner that searching of all the claims, at least when limited to an elected sequence, is not overlapping and that undue burden is placed on the Examiner if the Restriction is not made. Thus, Applicants

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believe that this Restriction Requirement does not meet both criteria as set forth in MPEP § 803 to be proper.

Further, with respect to election of a single sequence, Applicants respectfully disagree with the Examiner's suggestion that the sequences are unrelated. All sequences are related in the instant application by their identification as breast specific proteins and breast specific nucleic acids. Thus, reconsideration is respectfully requested for inclusion of at least 10 sequences as this constitutes a reasonable number for examination purposes in accordance with MPEP §803.04.

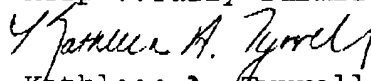
Reconsideration and withdrawal of this Restriction Requirement and sequence election requirement is therefore respectfully requested.

However, in an earnest effort to be completely responsive to this Restriction Requirement, Applicants elect to prosecute Group I, SEQ ID NO:75, with traverse.

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Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

Respectfully submitted,


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Reg. No. 38,350

Date: June 2, 2003

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June 2, 2003

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GROUP 1600

GROUP: 1631

FAX NUMBER: 1-703-872-9306

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SERIAL NO.: 10/082,828

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(including this sheet)

MESSAGE: Attached is a Response to the Restriction Requirement dated May 1, 2003.

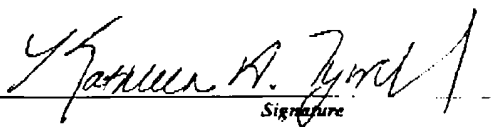
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AMENDMENT TRANSMITTAL LETTER (Large Entity)				Docket No. DEX-0247				
Applicant(s): Sun et al.								
Serial No. 10/082,828	Filing Date October 29, 2001	Examiner Cheyne D. Ly	Group Art Unit 1631					
Invention: COMPOSITIONS AND METHODS RELATING TO BREAST SPECIFIC GENES AND PROTEINS								
<u>TO THE COMMISSIONER FOR PATENTS:</u>								
Transmitted herewith is an amendment in the above-identified application. The fee has been calculated and is transmitted as shown below.								
CLAIMS AS AMENDED								
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST # PREV. PAID FOR	NUMBER EXTRA CLAIMS PRESENT	RATE	ADDITIONAL FEE			
TOTAL CLAIMS	19 -	20 =	0 x	\$18.00	\$0.00			
INDEP. CLAIMS	2 -	3 =	0 x	\$84.00	\$0.00			
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					\$0.00			
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT					\$0.00			
 <input checked="" type="checkbox"/> No additional fee is required for amendment. <input type="checkbox"/> Please charge Deposit Account No. _____ in the amount of _____ <input type="checkbox"/> A check in the amount of _____ to cover the filing fee is enclosed. <input checked="" type="checkbox"/> The Director is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-1619 <input checked="" type="checkbox"/> Any additional filing fees required under 37 C.F.R. 1.16. <input checked="" type="checkbox"/> Any patent application processing fees under 37 CFR 1.17.								
 _____ Signature			Dated: June 2, 2003					
Kathleen A. Tyrrell Reg. No. 38,350 Licata & Tyrrell P.C. 66 E. Main Street Marlton, NJ 08053 Tel: 856-810-1515 Fax: 856-810-1454			<table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="padding: 5px;">I certify that this document and fee is being deposited on _____ with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</td></tr><tr><td style="padding: 5px; text-align: center;">_____ Signature of Person Mailing Correspondence</td></tr><tr><td style="padding: 5px; text-align: center;">_____ Typed or Printed Name of Person Mailing Correspondence</td></tr></table>			I certify that this document and fee is being deposited on _____ with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	_____ Signature of Person Mailing Correspondence	_____ Typed or Printed Name of Person Mailing Correspondence
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<p>I hereby certify that this <u>Reply to Restriction Requirement</u> (Identify type of correspondence)</p> <p>is being facsimile transmitted to the United States Patent and Trademark Office (Fax. No. <u>703-872-9306</u>)</p> <p>on <u>June 2, 2003</u> (Date)</p> <p><u>Kathleen A. Tyrrell</u> (Typed or Printed Name of Person Signing Certificate)</p> <p><u>Kathleen A. Tyrrell</u> (Signature)</p> <p>Note: Each paper must have its own certificate of mailing.</p>			